DOCKET NO.: GALK-0007 Application No.: 10/748,891 Office Action Dated: May 3, 2005

REMARKS

Upon entry of the present amendments, claims 1-29 will be pending. Claims 1, 11, 14, 18, and 22 have been amended to positively recite "a partially radiopaque identifier." Claim 6 has been amended in light of the amendment to claim 1 (support for which is found in paragraph [0056]). New Figures 6, 7A, 7B, and 8 have been added (support for which can be found throughout the specification, for example claims 11-13 and paragraph [0056]), and the specification has been amended to describe the new figures. The Abstract has been amended in response to the Office Action's requirements for word count. New claims 28-29 have been added (support for which can be found throughout the specification, e.g., paragraph [0056]). No new matter has been added.

Drawings

New Figures 6, 7A, 7B, and 8 have been added to represent the claimed matter of claims 11-13 and 28-29.

35 U.S.C. §102 Claim Rejection based on Higgins

Claims 1, 14, 18, and 22 have been rejected under 35 U.S.C. §102(e) as allegedly being unpatentable over U.S. Patent No. 6,765,984 (Higgins). Applicant respectfully traverses this rejection as Higgins fails to teach or suggest Applicant's claimed invention.

One embodiment of the present invention is generally directed to comfort devices which comprise x-ray transparent compressible material and at least one partially radiopaque identifier which imparts information about the material onto a mammogram. The partially radiopaque identifier is permanently affixed to the material.

Higgins is directed to a "device for cushioning of compression surfaces." The Office Action cites to Higgins as disclosing "a portion of the identifier comprises indicia (Fig. 13A, 834) which impart information." Higgins describes "the grid 834 may be formed by cutting notches, molding indents, and the like" (Col. 8, lines 59-60). Significantly, one skilled in the art would understand that the grid 834 would *not* impart information onto a mammogram. To the contrary, such a grid would necessarily be x-ray transparent so as to not interfere with the imaging of the breast onto the mammogram. As admitted by the Office Action (¶ 11 at page 5), Higgins, therefore, fails to teach or suggest the claimed partially radiopaque identifier

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which imparts information about compressible material onto a mammogram. Applicant therefore requests that the rejection under § 102(e) be reconsidered and withdrawn.

35 U.S.C. §103 Claim Rejection based on Higgins and Hurwitz

Claims 1 through 27 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over Higgins in view of U.S. Patent No. 4,764,948 (Hurwitz). Applicant respectfully traverses this rejection as the combination of Higgins and Hurwitz fails to teach or suggest Applicant's claimed invention, and therefore *prima facie* obviousness has not been established.

Hurwitz discusses a "data marking system for medical x-rays, particularly mammograms." The data marking system of Hurwitz is primarily directed to providing patient-specific information (e.g., Col. 2, lines 63-68). Such systems include labels which are stenciled with patient-specific information "by simply handwriting or typewriting upon the label" (Col. 5, line 10). "The label is thereafter adhesively affixed" to the desired x-ray film cassette (Col. 5, lines 11-12). Accordingly, one skilled in the art would understand that this type of marking system is directed to specific information about a patient. Moreover, the label can be removed and re-used for the same patient for successive x-rays (Col. 4, lines 31-34).

With respect to claims 1-10, 14-17, 22, and 23-27, as amended, the cited art fails to teach or suggest the claimed "partially radiopaque identifier that is permanently affixed to the compressible material." Further, there is no motivation or suggestion to combine Higgins and Hurwitz in such a way as to come up with Applicant's claimed invention. Hurwitz contemplates using markers, that are generally removable and reusable, for patient-specific data. As such, one skilled in the art looking at Hurwitz would *not* have been motivated to modify Higgins in a way to create the claimed invention which comprises identifiers that are permanently affixed to compressible material and impart information about that compressible material. The Office Action, therefore, fails to establish a *prima facie* case of obviousness of claims 1-10, 14-17, 22, and 23-27, and Applicant respectfully requests that the 103 rejections over Higgins and Hurwitz be reconsidered and withdrawn.

As to claims 11-13 and 18-21, the Office Action admits that the cited art does not describe an identifying cover having radiopaque indicia (¶ 11, page 8). For this reason alone, prima facie obviousness has not been established because "all the claim limitations must be

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taught or suggested by the prior art." M.P.E.P. §2143.03. Further, the Office Action provides no factual basis for its conclusion "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a disposable identifying cover comprising x-ray transparent material adapted with a partially radiopaque identifier, for cost savings." Applicant asserts that the cited art fails to provide any suggestion whatsoever to modify either Higgins or Hurwitz or any combination of the two to utilize an identifying cover having radiopaque indicia. Because the Office Action fails to establish a *prima facie* case of obviousness of claims 11-13 and 18-21, Applicant respectfully requests that the 103 rejections over Higgins and Hurwitz be reconsidered and withdrawn.

Applicant asserts that newly added claims 28-29 are free of the cited art because they depend from claim 11.

In light of the foregoing, Applicant asserts that neither Higgins nor Hurwitz alone or in combination teach or suggest all of the elements of claims 1-29. As such, this application is in condition for allowance. Applicant invites the examiner to contact the undersigned at (215) 557-5965 to clarify any unresolved issues raised by this response.

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